

Concerned Citizens for St. John * Earthjustice * Lambert Law Firm * Lawyers Committee for Civil Rights Under Law * Louisiana Environmental Action Network * University Network for Human Rights et al.

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Re: Requesting a Meeting; Opposition to Denka's Request for Reconsideration of EPA's Toxicological Review of Chloroprene (RFC 17002)

Dear Dr. Vandenberg,

The undersigned groups respectfully request a meeting to discuss EPA's process for the *Request for Reconsideration of the Toxicological Review of Chloroprene* (RFC 17002), submitted by Denka Performance Elastomer LLC (Denka).¹ In addition to discussing the request for correction and request for reconsideration (and supporting materials) submitted by Denka, we would like to discuss both the *Third Party Correspondence (RFC 17002); Objection to RFC regarding IRIS Toxicological Review of Chloroprene* submitted by Dr. Karl Brooks, PhD² and the *Third Party Correspondence (RfR 17002A: Response to Denka Request for Reconsideration* submitted by Marco Kaltofen, PhD, PE and Keeve Nachman, PhD.³ The purpose of this meeting is to address concerns regarding the reconsideration process itself and Denka's suggestion that EPA might reconsider the chloroprene risk value in light of Denka's request for reconsideration.⁴ We seek to ensure that EPA considers community and scientific voices regarding this matter, and ask EPA to follow its usual scientific protocols and decide not to reconsider the robust and well-supported 2010 IRIS assessment.

¹ EPA, EPA Information Quality Guidelines - Requests for Correction and Requests for Reconsideration Submitted to EPA (RFC 17002) (June 2017), <https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration>.

² Third Party Correspondence (RfC 17002) from Karl Brooks, PhD, to Tina Bahadori, PhD and Kristina Thayer, PhD PhD, NCEA (September 8, 2017), https://www.epa.gov/sites/production/files/2017-10/documents/response_to_denka_rfc_17002_re_chloroprene.pdf.

³ Third Party Correspondence (RfC 17002) from Marco Kaltofen, PhD and Keeve Nachman, PhD, John Hopkins University, to EPA (July 23, 2018), https://www.epa.gov/sites/production/files/2018-09/documents/rfr_17002a_3rd_party_correspondence.pdf.

⁴ Request of Reconsideration of Denial of Request for Correction (RfR 17002A), Jorge Lavastida and Robert E. Holden, Denka (July 23, 2018), https://www.epa.gov/sites/production/files/2018-08/documents/rfr_transmittal_ltr_7-23-2018_n3630834x7a3a0.pdf.

EPA's 2010 IRIS assessment of chloroprene concluded that chloroprene is "likely to be carcinogenic to humans" through a mutagenic mode of action and with the primary exposure route being the inhalation pathway.⁵ The conclusion in the assessment was based on a comprehensive and systematic review of the available evidence on chloroprene toxicity. An inhalation unit risk (IUR) was set based on the available toxicological studies on increased incidence of tumors in a number of organ systems observed in both rat and mice and epidemiological studies of occupational workers, which showed an increased risk of liver cancer and lung cancer among workers. IRIS concluded based on the best available science that: "These tumors generally appeared earlier with increasing exposure level and showed statistically significantly increasing trends with increasing exposure level [to chloroprene]."⁶ Moreover, chloroprene's chemical structure is similar to known human carcinogens 1,3-butadiene and vinyl chloride, which provides an additional level of evidence to support the conclusion that chloroprene is a likely carcinogen. IRIS also determined that this chemical operates with a mutagenic mode of action for carcinogenicity, such that early-life exposure to babies, young children, or *in utero*, causes increased lifetime cancer risk.⁷

Based on these studies and the weight of the evidence, the IUR for cancer from chloroprene was set at 0.0003 per $\mu\text{g}/\text{m}^3$ for adult-only exposure through inhalation. IRIS also determined that it is necessary to account for increased vulnerability from early-life exposure, such that the more protective value of 0.0005 per $\mu\text{g}/\text{m}^3$ should be used to calculate cancer risks.⁸

IRIS's evidence and conclusions are directly supported by or consistent with findings of similarly highly regarded, scientific agencies, like the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC), which conclude that based on available evidence chloroprene is classified as "reasonably anticipated to be a human carcinogen" (NTP) and it is "possibly carcinogenic to humans" (IARC).⁹ Each institution – EPA, NTP, and IARC are highly reputable, respected, and known to conduct robust, independently peer-reviewed research on the toxicity of chemicals. The high standards set by each of these agencies results in chemical assessments that are both unbiased and reliable.¹⁰

An EPA Office of Air Quality Planning and Standards (OAQPS) internal memo on the *Preliminary Risk-Based Concentration Value for Chloroprene in Ambient Air* by Kelly Rimer, Leader of the Air Toxics Assessment Group, in the Health and Environmental Impacts Division of OAQPS, in reliance on the 2010 IRIS value, states,

⁵ EPA, Toxicological Review of Chloroprene, EPA/635/R-09/010F (Sept 2010), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1021tr.pdf ("IRIS 2010") and EPA, IRIS Chemical Assessment Summary – Chloroprene (Sept 2010), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1021_summary.pdf ("IRIS Summary 2010").

⁶ IRIS 2010 at 148.

⁷ IRIS Summary 2010 at 17.

⁸ IRIS 2010 at 109-11, 148.

⁹ NTP, Report on Carcinogens, Fourteenth Edition – Chloroprene (2016), attached as Attachment 1; IARC, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 71 – Chloroprene, attached as Attachment 2.

¹⁰ Similarly, California's Office of Environmental Health Hazard Assessment has long recognized chloroprene as a chemical "known to cause cancer." <https://oehha.ca.gov/proposition-65/cmr/chloroprene-cobalt-sulfate-heptahydrate-and-fenoxycarb-listed-known-cause-cancer> (listing chloroprene as a carcinogen in June 2000).

Under EPA's air toxics risk management framework, a cancer risk of 100-in-1 million is generally described as the upper limit of acceptability for purposes of risk-based decisions. Cancer risks at or below 1-in-1 million indicate little potential for cancer risk in the air toxics program. When existing source emissions are too high to achieve the 1-in-1 million level and controls are being considered, EPA is interested in controls that reduce off-site exposure concentrations associated with cancer risks to no higher than approximately 1-in-1 million for as much of the nearby population as feasible.¹¹

The memo goes on to acknowledge that:

[T]he 100-in-1 million cancer-risk based comparison level and the 1-in-1 million cancer-risk based comparison levels for chloroprene are 0.2 $\mu\text{g}/\text{m}^3$, and 0.002 $\mu\text{g}/\text{m}^3$ respectively. At a minimum, [the memo] recommend[s] that [Denka] aims for emission reductions such that the maximum annual average chloroprene concentration is no higher than 0.2 $\mu\text{g}/\text{m}^3$ at the highest modeled off-site location...it is preferable to have the chloroprene concentration at the highest modeled census block as close to 0.002 $\mu\text{g}/\text{m}^3$ as reasonably achievable.¹²

It is not clear from this letter whether OAQPS used 0.0003 per $\mu\text{g}/\text{m}^3$ or 0.0005 per $\mu\text{g}/\text{m}^3$, which is needed to protect public health, including children, from higher vulnerability to cancer that can result from exposure to chloroprene early in life. Regardless, EPA's letter and an analysis of the current air monitoring data make clear that the levels of chloroprene and resulting health risk are currently unacceptable, and far too high for community members in LaPlace, LA.¹³ Recent air monitoring data from 2016-19 show elevated levels of chloroprene that are far higher than 0.2 per $\mu\text{g}/\text{m}^3$ and 0.002 per $\mu\text{g}/\text{m}^3$ – including at a local hospital, elementary and high schools, and other community locations – that demonstrate the need for action to protect public health.¹⁴

It is important to the community for EPA to continue relying on the IRIS assessment to reduce the unhealthy levels of chloroprene Denka is emitting in LaPlace, LA, to get emissions down and end the currently unacceptable levels of cancer risk. It is essential for EPA's IRIS program to

¹¹ Memo from Kelly Rimer, Leader, Air Toxics Assessment Group, Health & Env'tl Impacts Div., OAQPS, to Frances Verhalen, P.E., Chief, Air Monitoring/Grants Section, EPA Region 6, Re: Preliminary Risk-Based Concentration Value for Chloroprene in Ambient Air (May 5, 2016) ("2016 EPA Memo"), <https://www.epa.gov/sites/production/files/2016-06/documents/memo-prelim-risk-based-concentrations050516.pdf>.

¹² *Id.*

¹³ The undersigned groups believe that EPA's benchmark of presumed unacceptability (100-in-1 million) is far too high for any given source category, as discussed in prior comments submitted on EPA's Cumulative Risk Assessment Request for Information. See, e.g., Comments of Earthjustice, NRDC, et al. on Request for Information and Citations on Methods for Cumulative Risk Assessment at 9, 38-40 (May 1, 2013), <https://www.regulations.gov/document?D=EPA-HQ-ORD-2013-0292-0132> (filed June 28, 2013), attached as Attachment 3. It is important and "preferable," as EPA's memo states, to reduce the ambient air concentration down to the level needed to avoid a cancer risk above 1-in-1 million. 2016 EPA Memo at 1.

¹⁴ See EPA, Denka Air Monitoring Summary Sheet, May 25, 2016 – April 29, 2019, see also EPA, DENKA Air Monitoring Summary Sheet, May 25, 2016-April 29, 2019, https://www.epa.gov/sites/production/files/2019-05/documents/r6_summary_through_april_29_2019.pdf; <https://deq.louisiana.gov/index.cfm?md=pagebuilder&tmp=home&pid=denka&id=2425> (average values in May 2018 at monitors ranged from 0.35 to 2.26 per $\mu\text{g}/\text{m}^3$, which are orders of magnitude higher than the levels threatening cancer risk that EPA deems unacceptable).

leave at rest the final, peer-reviewed value it issued in 2010 after completing the usual, scientific IRIS protocol.

EPA has already reconsidered this value once at Denka's request, and determined that it should stand, and there is no valid scientific reason for EPA to question or revisit the IRIS value now. In 2018, EPA denied Denka's request for correction (RfC), finding that the underlying review was consistent with EPA's Information Quality Guidelines.¹⁵ Denka had 90 days to submit a request for reconsideration (RfR) thereafter, such that it was due by April 25, 2018. Instead, Denka submitted a request for a 90-day extension of this date, days before its opportunity to submit the RfR expired. EPA granted the extension, and Denka submitted its RfR on July 23, 2018. On July 19, 2018 (only days before the RfR was submitted) EPA staff met with officials from the Louisiana Department of Environmental Quality, Denka, and Ramboll (a consulting group hired by Denka) to discuss a newly developed physiologically based pharmacokinetic (PBPK) model by Ramboll that resulted in a cancer-risk estimate far less stringent than the IRIS assessment derived.¹⁶ On July 24, 2018, Denka sent a letter to EPA suggesting that particular EPA staff (*i.e.*, Paul Schlosser) would be "go[ing] over the model," and stating that Denka was "pleased to hear that EPA intends to give high priority to the PBPK model evaluation and we look forward to receiving an updated timeline for the evaluation process."¹⁷ During the meeting, it appears that Denka believes EPA agreed to review the draft model, suggest improvements and upon revision, and arrange for some kind of additional review of the model.

We are highly concerned that Denka's description of EPA's statements suggests that IRIS may be engaging in or considering a process that is out of step with its own IRIS protocol and guidelines, and that, if followed, would represent an erosion of the integrity of the science assessments EPA's research staff conducts and the science-based actions that communities rely on for protections. Furthermore, existing agency documentation suggests that the PBPK models are in need of "better methods or implementation, and the characterization of uncertainty and variability in PBPK models is not yet a sufficiently standard practice."¹⁸ Consequently, such level of uncertainty and variability in PBPK modeling does not result in the ability to rely on such modeling as opposed to the sound science and robust weight of evidence provided in the available toxicological and epidemiological studies that IRIS relied upon for the 2010 chloroprene assessment.

Residents of LaPlace, LA face far too much toxic air pollution, and it has now been years since EPA first acknowledged that and began working to address this problem, after the 2011 National Air Toxics Assessment (NATA) showed cancer risks that are as high as 826-in-1 million for this community.¹⁹ The most recent NATA, released in 2018 and utilizing data from 2014, found

¹⁵ EPA Response to RfC 17002, Jennifer Orme-Zavaleta, PhD, NCEA, to Robert Holden, Denka (January 25, 2018), https://www.epa.gov/sites/production/files/2018-01/documents/epa_response_to_mr_holdren_jan_25_2018_complete.pdf.

¹⁶ Summary of Meeting Action Items, Event Title: Chloroprene Request for Correction/Request for Reconsideration (July 19, 2018), https://cfpub.epa.gov/ncea/iris2/event_attachment.cfm?layout=none&attach_id=544; the model has not completed an independent peer-review process.

¹⁷ Letter from Patrick A. Walsh, Denka, to John Vandenberg, PhD, NCEA (July 24, 2018), attached as Attachment 4.

¹⁸ EPA, Uncertainty and Variability in Physiologically Based Pharmacokinetic Models: Key Issues and Case Studies, EPA/600/R-08/090 (Aug. 2008), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=477286.

¹⁹ EPA, EPA in Louisiana – LaPlace, Louisiana Background Information (2016), <https://www.epa.gov/la/laplace-louisiana-background-information>.

cancer risks in this community are as high as 1505-in-1 million, driven primarily by chloroprene and ethylene oxide emissions.²⁰

Based on EPA's most current data, the parishes of St. John the Baptist and St. Charles have the census tracts with the highest cancer risk in the United States. Residents here live in what is sometimes described as "Cancer Alley," a geographic area that represents one of the most polluted parts in the country, and is also their home, where they should be able to be safe and healthy in their daily lives. The 2010 chloroprene risk value provides a baseline value that demonstrates this community needs a greater level of protection for residents from chloroprene pollution. EPA should follow through with additional action to protect the community, as discussed in its 2016 Action Plan for LaPlace, Louisiana, not spend time weakening or questioning the robust science in the 2010 IRIS assessment.²¹

EPA should not evaluate or undertake yet another review of the IRIS value, under EPA's own policy, when the 2010 chloroprene risk value is based on the best available science. Instead, EPA must continue to use and apply the 2010 chloroprene risk value to applicable assessments and cannot lawfully ignore the value in regulatory and enforcement processes. Rather than spending time questioning this well-supported health risk value, EPA should instead focus on completing IRIS assessments that are long overdue for chemicals that do not have an IRIS evaluation based on the best available science.

Community groups exposed to emissions from Denka and directly affected by EPA's actions respectfully request the opportunity to meet with EPA, to voice concerns regarding the process, and to receive information from EPA regarding the process.

Therefore, we respectfully request a meeting with you and any other appropriate EPA staff. Please contact Michelle Mabson at mmabson@earthjustice.org, (202) 667-4500 (ext. 5254), or Emma Cheuse at echeuse@earthjustice.org (ext. 5220) to arrange a meeting at your earliest convenience.

Sincerely,

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²⁰ EPA, 2014 National Air Toxics Assessment (2018), <https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results>; Sharon Lerner, *A Tale of Two Toxic Cities*, *The Intercept* (Feb. 24, 2019), <https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/> at Table: 109 Air Pollution Hotspots.

²¹ See EPA Action Plan (June 2016), <https://www.epa.gov/sites/production/files/2016-06/documents/epa-laplace-action-plan.pdf>.

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